		Case 3:07-cv-02940-SI	Document 10	5 File	ed 05/02/2008	Page 1 of 9				
FENWICK & WEST LLP ATTORNEYS AT LAW SAN FRANCISCO	1 2 3 4 5 6 7 8	DEAN S. KRISTY (CSB NO. 157646)  CHRISTOPHER J. STESKAL (CSB NO. 212297) CATHERINE D. KEVANE (CSB NO. 215501)  EMILY ST. JOHN COHEN (CSB NO. 239674) CHRISTINE VOGELEI (CSB NO. 239843)  FENWICK & WEST LLP 555 California Street, 12th Floor  San Francisco, CA 94104 Telephone: (415) 875-2300  Facsimile: (415) 281-1350 smuck@fenwick.com dkristy@fenwick.com csteskal@fenwick.com csteskal@fenwick.com ecohen@fenwick.com								
	10 11	Attorneys for Defendants Connetics Corp., John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans								
	12		UNITED STA	TES DIS	TRICT COURT					
	13	NORTHERN DISTRICT OF CALIFORNIA								
	14	SAN FRANCISCO DIVISION								
	15 16 17 18 19 20 21 22	IN RE CONNETICS COR SECURITIES LITIGATIO	N	DECLA STESK DEFEN PLAIN	AL IN SUPPOR IDANTS' MOTI IIFF'S SECONI DLIDATED CLA	ON TO DISMISS D AMENDED ASS ACTION				
	<ul><li>23</li><li>24</li><li>25</li><li>26</li><li>27</li></ul>									
	28	STESKAL DECLARATION ISO	MOTION			CASE NO. C 07.02040 SI				

TO DISMISS SAC

CASE NO. C 07-02940 SI

6

11

9

13

FENWICK & WEST LLP
ATTORNEYS AT LAW
SAN FRANCISCO

21

22

23

24

25

26

27

28

I, Christopher J. Steskal, declare as follows:

I am an attorney admitted to practice before this Court. I am a partner with the law firm of Fenwick & West LLP, counsel of record for defendants Connetics Corp. ("Connetics"), John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans in this action. I have personal knowledge of the matters set forth herein and, if called upon, could testify competently thereto.

- 1. Attached as Exhibit 1 is a true and correct copy of the transcript of Connetics' conference call on April 26, 2005. This document is quoted at paragraphs 58, 120, and 263-264 of the Second Amended Complaint.
- Attached as Exhibit 2 is a true and correct copy of the transcript of Connetics' conference call on January 25, 2005. This document is quoted at paragraphs 240-244 of the Second Amended Complaint.
- 3. Attached as Exhibit 3 are true and correct copies of excerpts from Connetics' Form 10-K/A for the fiscal year ended December 31, 2001, filed with the SEC on or about March 29, 2002.
- 4. Attached as Exhibit 4 are true and correct copies of excerpts from Connetics' Form 10-K/A for the fiscal year ended December 31, 2002, filed with the SEC on or about December 2, 2003.
- 5. Attached as Exhibit 5 are true and correct copies of excerpts from Connetics' Form 10-K for the fiscal year ended December 31, 2003, filed with the SEC on or about March 15, 2004. This document is quoted at paragraph 158 of the Second Amended Complaint.
- 6. Attached as Exhibit 6 are true and correct copies of excerpts from Connetics' Form 10-K for the fiscal year ended December 31, 2004, filed with the SEC on or about March 16, 2005. This document is quoted at paragraphs 246-251 of the Second Amended Complaint.
- 7. Attached as Exhibit 7 are true and correct copies of excerpts from Connetics' Form 10-K/A for the fiscal year ended December 31, 2005, filed with the SEC on or about July 25, 2006. This document is quoted at paragraphs 57, 61 and 187-192 of the Second Amended Complaint.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

8.	Attached as Exhibit 8 is a true and correct copy of Connetics' Form 8-K and Ex.
99.1 attach	ned thereto, filed with the SEC on or about May 24, 2002. This document is quoted a
paragraph	68 of the Second Amended Complaint.

- 9. Attached as Exhibit 9 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about January 27, 2004. This document is quoted at paragraphs 208-209 of the Second Amended Complaint.
- 10. Attached as Exhibit 10 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about March 24, 2004. This document is quoted at paragraphs 80-81 of the Second Amended Complaint.
- Attached as Exhibit 11 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about May 4, 2004. This document is quoted at paragraphs 210-212 of the Second Amended Complaint.
- 12. Attached as Exhibit 12 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about October 25, 2004. This document is quoted at paragraphs 226-227 of the Second Amended Complaint.
- 13. Attached as Exhibit 13 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about January 25, 2005. This document is quoted at paragraphs 238-239 of the Second Amended Complaint.
- 14. Attached as Exhibit 14 is a true and correct copy of Connetics' Form 8-K and Ex. 99.3 attached thereto, filed with the SEC on or about April 18, 2005. This document is quoted at paragraph 254 of the Second Amended Complaint.
- 15. Attached as Exhibit 15 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about April 26, 2005. This document is quoted at paragraphs 116-117 and 260-261 of the Second Amended Complaint.
- 16. Attached as Exhibit 16 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about June 13, 2005. This document is quoted at paragraphs 272-273 of the Second Amended Complaint.
  - 17. Attached as Exhibit 17 is a true and correct copy of Connetics' Form 8-K and Ex. 2 CASE NO. C 07-02940 SI

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

99.1 attached thereto, filed with the SEC on or about August 2, 2005	99.1	attached	thereto.	filed	with	the	SEC	on or	about	August	2.	2005.
--	------	----------	----------	-------	------	-----	-----	-------	-------	--------	----	-------

- 18. Attached as Exhibit 18 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about May 3, 2006. This document is quoted at paragraphs 177 and 298-299 of the Second Amended Complaint.
- 19. Attached as Exhibit 19 is a true and correct copy of Connetics' Form 8-K and Ex. 99.1 attached thereto, filed with the SEC on or about July 10, 2006. This document is quoted at paragraph 182 of the Second Amended Complaint.
- 20. Attached as Exhibit 20 is a true and correct copy of a Form 8-K with the SEC's General Instructions relating to the use of such forms.
- 21. Attached as Exhibit 21 are true and correct copies of Forms 4 filed on behalf of Thomas G. Wiggans with the SEC between July 1, 2001 and July 9, 2006. These documents are quoted at paragraphs 328-330 and 391 of the Second Amended Complaint.
- 22. Attached as Exhibit 22 are true and correct copies of Forms 4 filed on behalf of John L. Higgins with the SEC between July 1, 2001 and July 9, 2006. These documents are quoted at paragraphs 328-330 and 391 of the Second Amended Complaint.
- 23. Attached as Exhibit 23 are true and correct copies of Forms 4 filed on behalf of C. Gregory Vontz with the SEC between July 1, 2001 and July 9, 2006. These documents are quoted at paragraphs 328-330 and 391 of the Second Amended Complaint.
- 24. Attached as Exhibit 24 are true and correct copies of Forms 3 and 4 filed on behalf of Lincoln Krochmal with the SEC between September 24, 2003 and January 19, 2005. These documents are quoted at paragraphs 331 and 335 of the Second Amended Complaint.
- 25. Attached as Exhibit 25 is a true and correct copy of Connetics' Schedule 14A Proxy Statement, filed with the SEC on or about April 21, 2006. This document is quoted at paragraphs 315 and 334 of the Second Amended Complaint.
- 26. Attached as Exhibit 26 is a true and correct copy of Section 6010.5 of the United States Food and Drug Administration ("FDA") Manual of Policies and Procedures for the Center for Drug Evaluation and Research ("FDA Manual"). This section of the FDA Manual can be found on the FDA's website at http://www.fda.gov/cder/mapp/6010.5.pdf.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

ENWICK & WEST LL. ATTORNEYS AT LAW SAN FRANCISCO
--

	27.	Attached as Exhibit 27 is a true and correct copy of Section 7412.2 of the FDA
Manua	al. This	section of the FDA Manual can be found on the FDA's website at http://www.fda.
gov/co	der/man	p/7412-2.pdf.

- 28. Attached as Exhibit 28 is a true and correct copy of a publicly available Special Report from FDA Consumer Magazine titled "The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective." This report is available on the FDA's website at http://www.fda.gov/ fdac/special/testtubetopatient/drugreview.html.
- 29. Attached as Exhibit 29 is a true and correct copy of an excerpt of a publicly available document titled "Drug Development and Review Definitions" available on the FDA's website at http://www.fda.gov/cder/about/smallbiz/definitions.htm.
- 30. Attached as Exhibit 30 is a true and correct copy of a publicly available document titled "Final Printed Labeling." This document can be found on the FDA's website at http://www.fda.gov/cder/foi/nda/2000/50-756\_Benzaclin\_prntlbl.pdf ("BenzaClin labeling"). The BenzaClin labeling states on page six that "[b]enzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies" and that it "induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment."
- 31. Attached as Exhibit 31 is a true and correct copy of a publicly available document titled "Approval Letter." This document can be found on the FDA's website at http://www.fda. gov/cder/foi/nda/2000/50-756\_Benzaclin\_Approv.pdf ("BenzaClin Approval Letter"). The BenzaClin Approval Letter states that the FDA has "completed the review of this application, as amended, and [has] concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text." It also states, "we remind you of your post marketing commitments...to conduct a dermal carcinogenicity study."
- 32. Attached as Exhibit 32 is a true and correct copy of a publicly available document titled "Final Printed Labeling." This document can be found on the FDA's website at http://www.fda.gov/cder/foi/nda/2002/50-741\_DUAC Topical Gel\_Prntlbl.pdf ("Duac labeling"). The Duac labeling states on page five that "[b]enzoyl peroxide has been shown to be a tumor STESKAL DECLARATION ISO MOTION

4

1

6

7

10

14

FENWICK & WEST LLP
ATTORNEYS AT LAW
SAN FRANCISCO

16

promoter and progression agent in a number of animal studies" and that it "induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment."

- 33. Attached as Exhibit 33 is a true and correct copy of a publicly available document titled "Approval Letter." This document can be found on the FDA's website at http://www.fda. gov/cder/foi/nda/2002/50-741\_DUAC Topical Gel\_Approv.pdf ("Duac Approval Letter"). The Duac Approval Letter states that the FDA has "completed the review of this application, as amended, and [has] concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text." It also states, "we remind you of your post-marketing study commitments...to performing dermal carcinogenicity testing by combination drug product."
- 34. Attached as Exhibit 34 is a true and correct copy of a publicly available document titled "Approved Labeling." This document can be found on the FDA's website at http://www.fda.gov/cder/foi/nda/2000/20-748\_Differin\_Prntlbl.pdf ("Differin labeling"). The Differin labeling states on page four that "carcinogenicity studies... have been conducted in mice... and in rats" in which "increased incidence of benign and malignant pheochromocytomas in the adrenal medullas of male rats was observed."
- 35. Attached as Exhibit 35 is a true and correct copy of a publicly available document titled "Approval Letter." This document can be found on the FDA's website at http://www.fda. gov/cder/foi/nda/2000/20-748 Differin Approv.pdf ("Differin Approval Letter"). The Differin Approval Letter states that the FDA has "completed the review of this application, as amended, and [has] concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text."
- 36. Attached as Exhibit 36 is a true and correct copy of a publicly available document titled "Final Printed Labeling." This document can be found on the FDA's website at http://www.fda.gov/cder/foi/label/2002/16921s21s22s25lbl.pdf ("Retin-A labeling"). The Retin-A labeling states on page two that "[c]utaneous squamous cell carcinomas and papillomas in the treatment area were observed in some female mice. A dose-related incidence of liver tumors in male mice was observed at those same doses."

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

37. Attached as Exhibit 37 is a true and correct copy of a publicly available documen
titled "NDA 16-921 S021/022/025." This document can be found on the FDA's website at
http://www.fda.gov/cder/foi/appletter/2002/16921s021ltr.pdf ("Retin-A Approval Letter"). The
Retin-A Approval Letter states that the FDA has "completed the review of these supplemental
applications, and [has] concluded that adequate information has been presented to demonstrate
that the drug product is safe and effective for use as recommended in the agreed upon enclosed
labeling text."

- 38. Attached as Exhibit 38 is a true and correct copy of a publicly available document titled "Final Printed Labeling." This document can be found on the FDA's website at http://www.fda.gov/cder/foi/nda/2000/50777\_Protopic\_Prntlbl.pdf ("Protopic labeling"). The Protopic labeling states on page eleven that "a statistically significant elevation in the incidence of pleomorphic lymphoma in high dose male (25/50) and female animals (27/50) and in the incidence of undifferentiated lymphoma in high dose female animals (13/50) was noted in the mouse dermal carcinogenicity study."
- 39. Attached as Exhibit 39 is a true and correct copy of a publicly available document titled "Approval Letter." This document can be found on the FDA's website at http://www.fda. gov/cder/foi/nda/2000/50777\_Protopic\_Approv.pdf ("Protopic Approval Letter"). The Protopic Approval Letter states that the FDA has "completed the review of this application, as amended, and [has] concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text."
- 40. Attached as Exhibit 40 is a true and correct copy of a publicly available document titled "Aldara." This document can be found on the FDA's website at http://www.fda.gov/cder /foi/label/2004/20723se1-015 aldara lbl.pdf ("Aldara labeling"). The Aldara labeling states on page nine that "[i]n a dermal mouse carcinogenicity study... [a]n increased number of skin papillomas was observed in vehicle cream control group animals at the treated site only."
- 41. Attached as Exhibit 41 is a true and correct copy of a publicly available document titled "NDA 20-723/S-001." This document can be found on the FDA's website at http://www.fda.gov/cder/foi/appletter/2001/20723s1ltr.pdf ("Aldara Approval Letter"). The

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

Aldara Approval Letter states that the FDA has "completed the review of this application, as
amended, and [has] concluded that adequate information has been presented to demonstrate that
the drug product is safe and effective for use as recommended in the agreed upon enclosed
labeling text."

- 42. Attached as Exhibit 42 are true and correct copies of excerpts from a publicly available document titled "Administrative Documents." This document can be found on the FDA's website at http://www.fda.gov/cder/foi/nda/2003/21-535 Clobex Admindocs.pdf ("Clobex Director Review"). The Clobex Director Review states on page four that a "Medical Officer" and "Team Leader" recommended after a "safety" review of Clobex that "the action taken for the new drug application of [Clobex] be that of non-approvable." Page seven of the Clobex Director Review also indicates, however, that the division director overruled the Medical Officer and Team Leader and concluded that "[t]his NDA is sufficient for approval since the sponsor has committed to perform the recommended post-marketing studies, both non-clinical and clinical, and has accepted the final draft labeling proposed to sponsor."
- 43. Attached as Exhibit 43 is a true and correct copy of a publicly available document titled "Approval Letter." This document can be found on the FDA's website at http://www.fda. gov/cder/foi/nda/2003/21-535\_Clobex\_Approv.pdf ("Clobex Approval Letter"). The Clobex Approval Letter states that the FDA has "completed [its] review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text."
- 44. Attached as Exhibit 44 are true and correct copies of excerpts from a publicly available document titled "Center for Drug Evaluation and Research: Report to the Nation 2005," which can be found on the FDA's website at http://www.fda.gov/cder/reports/rtn/2005/ rtn2005.pdf.
- 45. Attached as Exhibit 45 is a true and correct copy of a financial analyst report issued by Wachovia Capital Markets, LLC on April 26, 2005.
- Attached as Exhibit 46 is a true and correct copy of a financial analyst report 46. issued by Jefferies & Co., Inc. on April 27, 2005.

47. Attached as Exhibit 47 is a true and correct copy of a financial analyst report
issued by Summer Street Research Partners on June 9, 2005.
48. Attached as Exhibit 48 is a true and correct copy of an October 30, 2002 National
Institutes of Health report entitled "Transgenic Mouse Models: Their Role in Carcinogen
Identification." This report is quoted at paragraph 56 of the Amended Complaint.
49. Attached as Exhibit 49 are tables summarizing defendants' stock sales and
holdings of Connetics stock during the period July 1, 2001 to July 9, 2006. The figures included
in these were compiled from the publicly available information contained in Exhibits 21 through
24.
50. Attached as Exhibit 50 is a table summarizing some of the meaningful cautionary
language related to Velac gel that Connetics publicly disclosed in its filings with the SEC and
included in its public statements. This table summarizes publicly available information contained
in Exhibits 1, 3-10, 12, 15 and 16.
51. Attached as Exhibit 51 is a true and correct copy of a chart showing Connetics'
historical stock prices from December 1, 2003 through December 28, 2006.
52. Attached as Exhibit 52 is a true and correct copy of a publicly available Report for
Congress prepared by the Congressional Research Service titled "The U.S. Drug Approval
Process: A Primer." The document can be found at http://www.law.umaryland.edu/marshall/
crsreports/crsdocuments/RL30989.pdf.
I declare under penalty of perjury under the laws of the United States of America that the
foregoing is true and correct to the best of my knowledge, information and belief.
Executed this 2nd day of May 2008, at San Francisco, California.
By: <u>/s/ Christopher J. Steskal</u> Christopher J. Steskal
Christopher J. Steskar
25251/00402/DOCS/1901702.1